



510(k) Summary

Device	AEM® Single-Use Suction Irrigation Instrument	
Owner	Encision, Inc. 6797 Winchester Circle Boulder, CO 80301 Phone: (303) 444-2600 Fax: (303) 444-2693	AUG 26 2013
Contact	James W. Lewis Vice President, Regulatory Affairs and Quality Assurance	
Date of Summary	26 June 2013	
Device Classification	<i>Trade name</i> AEM Disposable Suction Irrigation Electrode <i>Common name</i> Active suction/irrigation laparoscopic monopolar electrosurgical electrode with AEM technology <i>Classification</i> Classification name: Electrosurgical, Cutting & Coagulation & Accessories Classification number: 21 CFR 878.4400 Product Code: GEI Class: 2 FDA Panel: General and Plastic Surgery	
Primary Predicate	<i>Trade Name</i> AEM Suction Irrigation Electrode <i>Manufacturer</i> Encision Inc <i>Cleared by</i> 510(k): K100711	
Secondary Predicate	<i>Trade Name</i> AEM Disposable Suction Irrigation Electrode and Handset <i>Manufacturer</i> Encision Inc <i>Cleared by</i> 510(k): K122580	

Device Description

General description	AEM Single-Use Suction Irrigation Instruments are <ul style="list-style-type: none"> • Electrosurgical accessories, which combine <ul style="list-style-type: none"> – Classic active electrode functions of cutting and coagulating tissue with monopolar high-frequency electrical energy – Shape, size and reach to work laparoscopically or endoscopically – Elimination of stray-energy emission outside surgeon view provided by AEM shielding and monitoring – Convenience/peace-of-mind provided by product provided clean and sterile from manufacturer to operating room – Convenience of providing suction or irrigation to the surgical site without having to swap instruments in and out of the cannula
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Device Description (continued)

General description (continued)	<ul style="list-style-type: none"> • Used to ablate, remove, resect, and coagulate soft tissue where associated hemostasis and visualization is required • For use in open, endoscopic, and laparoscopic surgical procedures
Specific description	<p>The instruments of this submission are configured to support foot-controlled laparoscopic electrosurgery</p> <ul style="list-style-type: none"> • Direct connection from instrument tip to electrosurgical unit foot-switched power outlet via AEM Cord and Monitor • Suction irrigation channel adapted directly to commercially available suction-irrigation valves • Working length: 32 cm • Fits within 5.5 mm diameter cannula
Intended Use	<p>Sterile, single-patient-use electrosurgical accessories intended to conduct electrosurgical current for cutting and coagulation of tissue and/or to provide suction and irrigation functions to the surgical site. These accessories have applications in general endoscopy and laparoscopy procedures.</p> <p>AEM instruments incorporate the use of AEM technology and are intended for use with the AEM monitoring system and electrosurgical generators compatible with the AEM system</p>

Equivalence

Based on operating principles, intended use, technology, safety, and performance; these AEM Disposable Suction Irrigation Instruments are substantially equivalent to the combination of features and construction details of its predicate devices.

Electrode shaft and tip	<p>Identical to electrode shaft and tip of AEM Disposable Suction Irrigation Electrode in</p> <ul style="list-style-type: none"> • Design • Construction • Packaging • Sterility • Materials
Hub and adapter	<p>Identical to hub and adapter of AEM Suction Irrigation Electrode in</p> <ul style="list-style-type: none"> • Design • Construction • Material <p>Substantially equivalent to hub of AEM Disposable SI Electrode in sterility (slightly less packaged density for more effective sterilization)</p>

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Bench Testing

Verification and validation tests were performed in accordance with Design Control requirements per 21 CFR 820.30 and company quality system procedures.

Bench testing included

- Characterizing all essential specifications not covered by equivalent designs on production-equivalent units
- Successfully demonstrating no significant effect on primary specifications of production units due to
 - Aging (both with accelerated and real-time testing)
 - Shipping drop/shock/vibration

All testing successfully completed prior to release of product for sale.

Biocompatibility

Biocompatibility of all materials with direct or indirect contact with the patient verified through analogy with identical materials, processes, and uses from the predicate devices.

Sterility / Packaging / Shelf life

Packaging	<ul style="list-style-type: none"> • Product individually packaged in Tyvek pouch • Six individual pouches placed in cardboard shipping container
Sterilization method	<ul style="list-style-type: none"> • Sterilized in shipping boxes on pallets • Electron-beam irradiation by qualified contract sterilizer
Sterilization standard	Sterilized in accordance with ANSI-AAMI-ISO 11137-1:2006 guidelines
Aging validation	<p>Shelf life of product and packaging validated for sterility and function</p> <ul style="list-style-type: none"> • For, at least, one year shelf life by accelerated aging • Verified by real-time aging • Extended as data from aging tests demonstrate greater longevity on the shelf
Shelf-life communication	A "use by" date on all boxes and pouches containing product will indicate validated shelf life of the package

Conclusion

There are no significant differences between the subject instruments and their predicate devices which would raise new issues of safety and effectiveness, performance, function or intended use with respect to

- Electrosurgical application or performance
- Suction/irrigation performance
- AEM shield and monitoring performance.

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Technological similarities between the predicate devices and the proposed device also demonstrate equivalence.

Product testing of subject instruments and direct analogy with predicate device design and materials demonstrates acceptable safety and performance outcomes and successful attainment of all essential specifications for the devices.

AEM Single-Use Suction Irrigation Instruments are substantially equivalent in design, use, construction, and safety and effectiveness to their predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Encision, Inc.
Mr. James W. Lewis
Vice President, Regulatory Affairs and
Quality Assurance
6797 Winchester Circle
Boulder, Colorado 80301

August 26, 2013

Re: K131949
Trade/Device Name: AEM Disposable Suction Irrigation Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 26, 2013
Received: June 27, 2013

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

FOR **Peter D. Rumm -S**

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AEM® Single-Use Suction Irrigation Instrument
Premarket Notification

Section 4
INDICATIONS FOR USE

510(k) Number: K131949

Device Name: AEM Single-Use Suction Irrigation Instrument

Indications for Use:

Sterile, single-patient-use electrosurgical accessory intended to conduct electrosurgical current for cutting and coagulation of tissue and/or to provide suction and irrigation functions to the surgical site. These accessories have applications in general endoscopy and laparoscopy procedures.

AEM instruments incorporate the use of AEM technology and are intended for use with the AEM monitoring system and electrosurgical generators compatible with the AEM system.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

(Division Sign-Off)

Division of Surgical Devices

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